

**REMARKS**

Claims 1 and 7-17 stand presented rejected. Claims 1, 7, and 14 stand presently amended to respond to the Examiner's concerns. Claims 2-6, reflect the initially multiply dependent claims in the translation, and are cancelled.

Applicant's gratefully acknowledge the formal acceptance of the drawings and the priority claim under 35 U.S.C. §119 noted in the instant action.

Applicants have carefully considered the Office comments and reconsideration is respectfully requested. The application is now believed to be on condition for allowance and notice of this status is earnestly solicited.

No new matter has been added. Support for the amendments is found in the original claims and complete disclosure as discussed herein.

**1. Claims 1 and 7-17 presently rejected under 35 USC §112 (first and second paragraph)**

Claims 1, 7, and 14 specifically, and their dependent claims 8-13 and 15-17 stand presently rejected under 35 USC §112, first paragraph for failing to comply with the written description requirement; namely that one skilled in the relevant art would not have considered the claimed scope to be sufficiently disclosed within the application as filed.

Applicants have carefully considered the Office comments and request reconsideration. On the present record, in sustaining such a *prima facie* assertion the Office has necessarily taken two positions; first, a determination of the skill of one in the

art that excludes those versed in the use, generation, and manufacture of therapeutic insoles, and second that one of such low skill in the art would only seek literal definitions of phrases in the claims as the source of understanding and not from the entire integrated disclosure. Reconsideration of this position is respectfully requested.

It is well recognized that the claims are presumed to be supported by the entire submission (drawings, specification, claims, and the discussion of related art references within the disclosure) when considered as a whole (the integrated whole). It is similarly recognized that the burden is *extremely* high for the Office to establish the *prima facie* rejection under §112 (MPEP 2164.04), where the disclosure contains a teaching (of any reasonable kind) of the manner or process of the invention which correspond to the scope used in the claims when viewed by one skilled in the art. Such support, once found, must be taken as being in full compliance with the enablement requirement of 35 USC §112 unless there a reason to doubt the objective truth of the statements (and no such doubt has been raised by the Office). Here, it is proposed that there are ready teachings in the disclosure as to the use, position, operation, location etc. of the claim elements and that there is no reason raised by the Office in the record to doubt the truth of the specification. It is noted that the Office is to give *every deference* to the written description – even where the translation is from one cultural language (German) to another (English) necessarily requires the selection of English language phrase.

As a consequence, Applicants respectfully request reconsideration of the Office's position that there is insufficient distinctiveness in the disclosure for one skilled in the art. It is proposed that:

- (1) Correctly found, one skilled in the present art is specifically a podiatrist (MD-therapy involving feet) with familiarity of electronics and electronic measurement systems (extremely common in medical practice where each physician must use complex electronic systems daily), although other licensed physicians (MD's) are easily and suitably informed by their general skill in the orthopedic arts (see generally the subject matter), and
- (2) There is more than sufficient discussion and disclosure of both the specific medical nature involved with the instant orthopedic/therapeutic process for such a skilled physician/clinician to recognize a treatment involving the stimulation of proprioceptors (free nerve endings of the muscles (of a patient's feet)) in concert with the free nerve endings of the labyrinth (the organ medically recognized as governing balance) (see specifically page 4, first full through third paragraphs and thereafter) and for determining a location based on a medical need.

Applicants propose that since one skilled in the art would adequately be represented by a highly trained physician (MD) familiar with modern medical treatment involving electronic systems, and that such an individual, having read and considered the specifically as an integrated disclosure would readily understand: (i) diagnosing (a process required in therapy and known to the skilled person) a human having "problems of body balance", (ii) designating the form (shape) of therapeutic insoles to "stimulate"

the proprioceptors – nerve endings to body muscles and the labyrinth (known to be the inner ear organ governing balance) to provide the patient's brain with necessary nerve stimulation to correct body posture (e.g., body balance), and (iii) positioning the so-shaped proceptors, and ultimately (v) recognizing desired therapeutic insoles to correct the therapeutic problem.

Applicants acknowledge the less common “proprioceptors” phrase introduced (page 4, second para. as nerve endings as noted) but it is specifically discussed and the subject matter obviously involves medical treatment and those who are highly skilled in the medical arts readily scan such details with rapid understanding based on their training context – for example see the discussions in the related art identified in the translation. Similarly, the use of the phrase “proceptors” is employed in easy medical context (page 5 of the translation, first paragraph) as being stimulators acting upon the proprioceptors in the sole of the foot – which one of skill in the art would understand to be with the goal of correcting a diagnosed foot disorder (what ever a diagnosis may be there is no requirement for a claim to a specific diagnosis other than “foot disorder” within the context) to treat body balance.

Similarly, the use of the present system and method is focused to “treat problems of body balance” (page 4, first full para of the translation), of which an earlier solutions involving hand-made orthopedic insoles have proven unacceptable. Similarly, the cited art by the Office and Application all deal with correcting/addressing a perceived defect in the foot and the impact upon the human patient. Each suggests a solution different from the present application, but each reference would be known to one of skill in the art.

As noted earlier, it is proposed that one of skill in the therapeutic arts would also recognize the interrelation between Figs. 1 and 2 and the overall written description as process for generating an insole product for stimulating the “proprioceptors” on the sole of the foot as determined by a need to treat certain foot disorders recognized by those of skill in the art as negatively impacting body posture.

There is no requirement in the overall description to support the inherent medical training and knowledge within one having highly skilled medical training and none is required. Nor is there a requirement in the overall description (translation here) to follow a rigid discussion process of definition-then-discussion – the disclosure as a whole is viewed and considered as an integrated whole.

Ultimately, there must be a reasonable basis to question the enablement to raise the instant rejection, and this standard only exists when there is no evidence in the record absent undue experimentation (MPEP 2164.04) for one of skill in the art. A specification, such as the present disclosure, that contains the “evidence” (teaching) in general corresponding terms and scope of the claims when viewed by one of skill in the art must be taken as being in compliance with §112 1<sup>st</sup> para. Description and possession of a claimed subject matter may be shown in many ways, and the *prima facie* burden is upon the Office due to the presumption of an enabling written description. Consequently, because the subject matter is well discussed, it is respectfully proposed that such *prima facie* burden has not been achieved and that no undue experimentation is at issue.

The Office argues on page 2, last paragraph that “nowhere in the specification” is it stated that the phrase “patient’s/therapeutic predisposition” means “flatfoot,

splayfoot....”. Applicant respectfully notes that such a statement is not the standard required by 35 U.S.C. §112 first paragraph. The treatment of therapeutic predispositions (e.g. “certain foot disorders”) would involve “flatfoot, splay foot....” (see page 4 of translation, first para.). No leap of understanding is required for one skilled in the art. Nor does 35 U.S.C. §112 require mechanical or formulaic generation of definitions for claim phrase selection. Such a statements are not required to achieve acceptance under §112 and Applicants have not attempted to introduce a definition – only an obvious explanation of what one of skill in the subject matter art would understand having contemplated the entire disclosure. Reconsideration is requested.

The Office position (on page 2 and page 4 of the instant action) is that there is “no relationship between flatfoot, splayfoot, club foot....” with the claimed limitations and Applicant’s request reconsideration. It is proposed that on page 4 first paragraph of the translation, that a physician (MD) as one skilled in the therapeutic arts (which includes the diagnosing arts) would easily recognizes that the phrase “measuring the nature of the foot to produce the appropriate insoles which are made to react passively to certain foot disorders...” would readily recognize that the claims involve the treatment of various foot disorders (page 4, first para., line 3) that ultimately “treat problems of body balance” (page 4, second para., line 4) as such a physician would understand from their medical training. Again, no leap in knowledge is required and reconsideration is requested.

The Office position (on page 3, third para.) is necessarily two fold – first, that there is no definition for the phrase “externally determined predisposition” and second that there is a need for such a literal definition. The claims obviously involve a system,

arrangement or method for treating a patient having an earlier-existing predisposition (e.g., a foot disorder) and that a skilled physician-user of such a system, arrangement or method has received sufficient medical training to making the decisions necessary to make a location determination external to the system, arrangement, or method of operating to treat this earlier existing foot disorder (that there is a need to correct and where to correct). Claims 1, 7, and 14 require only that such proceptors 3, 4 be placed/located (an action verb-place or placing) under the patient's foot for scanning and this is readily disclosed. These claims do not claim the training to determine where to place/locate such proceptors 3, 4 as this determination is external and particular to the patient. As such, Applicants sought to include the phrase "externally determined" for clarity as to source to respond to the Office's earlier confusion. Now, this phrase has been removed upon the office suggestion.

Regarding the Office antecedent concern (page 3 first para. of the action) in claim 7, that "according to a patient's neurological therapy" lacks antecedent basis in the specification, Applicants request reconsideration. In taking such a position, the Office necessarily takes the awkward position that there is no support in the specification for manipulating (in some computer-based way), a scanned image of the underside of a patient's foot with proceptors there-under to treat (provide therapy to) a patient. Applicants propose that this stretch is without support where the substance of the disclosure involves converting (a/k/a manipulating) information (a/k/a the scanned data) from a scanned image by a computer to achieve treatment (a/k/a therapy) of a patient's neurology (a/k/a nerves or free nerve endings in the foot). The phrase in question is both

properly introduced with “A” as a noun – being therapy itself, and is in the “whereby” or explanatory portion of the final clause. The Office recognizes Applicant’s ability to retain their own lexicography and Applicants propose that the above discussion readily supports an antecedent basis within the specification for such a limitation.

In conclusion, Applicants respectfully request reconsideration and suggest that in view of the complete disclosure, when considered in total by one skilled in the necessary arts (a physician e.g., a podiatrist) the claim language is fully supported by the specification and that the claim language would be similarly readily understood.

In view of the above discussion, Applicants request reconsideration and submit that a *prima facie* rejection based on §112, first paragraph or second paragraph, has not been established and cannot be maintained with sufficient specificity recognizing the skill in the art and the content of the disclosure. Applicants therefore respectfully request withdrawal of the rejection to claims 1, 7-14, under 35 U.S.C. § 112, and written record of the same in the next Office communication. If required by the Office, or at Office suggestion, such recognition of the skill in the art may be supported by 37 C.F.R. §1.132 Affidavits or Declarations.

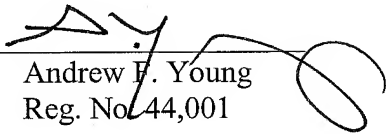
Should any additional discussion be appropriate to place the application in condition for allowance, the Examiner is respectfully requested to notify the undersigned for an immediate response.

While no fee is believed due herein, other than those enclosed, the Director is hereby authorized to charge said fee to Deposit Account No. 10-0100.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,  
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